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Hon. Tonianne J. Bongiovanni, U.S.M.J.
Clarkson S. Fisher Federal Building & U.S. Courthouse
402 East State Street
Trenton, New Jersey 08608

Re: *Arbutus Biopharma Corp et al. v. Pfizer Inc. et al.*, Case No. 3:23-cv-04200-ZNQ-TJB

Dear Judge Bongiovanni:

We represent the Plaintiffs along with our co-counsel for Arbutus Biopharma Corp., Morrison & Foerster LLP, and co-counsel for Genevant Sciences GmbH, Quinn Emanuel Urquhart & Sullivan, LLP. We write in opposition to Defendants' June 14 letter (ECF No. 79), which seeks an order compelling production of certain documents. For the reasons discussed below, the Court should deny Defendants' requests to the limited extent they are not already moot.

By way of background, this case concerns five patents that Defendants are infringing in connection with their manufacture and sale of a COVID-19 vaccine. The patents demonstrate Plaintiffs' cutting-edge scientific research regarding lipid nanoparticle ("LNP") technology. Although the merits of Plaintiffs' infringement claims are irrelevant to the discovery disputes at issue, Defendants' letter opens with a narrative about Plaintiffs' purportedly limited role in the development of the relevant technologies. That narrative is not only false but also a disingenuous made-for-litigation position: In 2018, Defendant BioNTech *paid for a license* to use Plaintiffs' technologies, which it described as "*the best lipid nanoparticle ["LNP"] technology*." ECF No. 1, ¶ 6. And in 2021, a lead vaccine development scientist at Defendant BioNTech said that the named inventor on Plaintiffs' patents gets "a lot of credit … for the LNP" used in the vaccine, which she said "is as important as the mRNA in the vaccine." ECF. No. 1, ¶ 49. Defendants cannot walk back those admissions now.

In any event, Plaintiffs have already produced or agreed to produce [redacted] An order compelling production of [redacted] should be denied because those materials are irrelevant, unduly burdensome to produce, and/or disproportionate to the needs of this case.

1. The Request For *Moderna* Documents Is Largely Moot And Should Otherwise Be Denied

The Court should deny Defendants' request for "[a]ll documents and things produced by Plaintiffs" in *Arbutus Biopharma Corp. v. Moderna Inc.*, No. 22-252 (D. Del.). *See* ECF NO. 79 at 2. The request is largely moot because Plaintiffs have already agreed to produce [redacted] *Id.* at 3. The Court should deny Defendants' request for those materials for several reasons.

First, what's good for the goose must be good for the gander. Despite their demands for materials Plaintiffs produced in *Moderna*, Defendants have outright refused to produce *any* of the documents they produced in *Alnylam Pharmaceuticals, Inc. v. Pfizer Inc., et al.*, C.A. No. 22-cv-336-CFC (D. Del.), a litigation that involves ***the same vaccine*** and ***same claimed subject matter*** at issue here. If Plaintiffs are required to produce documents from *Moderna*, then Defendants must similarly be required to produce documents from *Alnylam.* Defendants cannot have it both ways.

Second, many of the disputed documents are irrelevant because the claims and defenses in *Moderna* differ from those here. The vaccine in *Moderna* is not the vaccine here. Three patents asserted in *Moderna* are not asserted here. And two patents asserted here are not asserted in *Moderna.* In short, contrary to Defendants' assertion, *Moderna* documents are ***not*** "necessarily relevant to the claims and defenses in this case," and Plaintiffs are *not* "obligated to produce them." ECF No. 79 at 2-3. If anything, the requested documents concerning different products and patents will likely confuse and add further complication to this already complicated case. *See VLSI Tech. LLC v. Kirkland & Ellis LLP*, No. MC 18-63-RGK (PLAX), 2018 WL 6930769, at *3 (C.D. Cal. June 19, 2018) (the "demand for blanket production of seemingly all … documents from [a prior] litigation is overly broad [because it is] not limited to only those documents that relate to the claims at issue in the pending action. The prior case involved seventeen patents while the pending case involves eight patents, and while there may be [] some overlap of issues, there is not a total overlap of claims…."); *Orexo AB v. Actavis Elizabeth LLC*, No. CV 17-205-CFC, 2019 WL 6728637 (D. Del. Dec. 11, 2019) (risk of confusion outweighed probative value of producing documents relevant to a different product in a different case).

Third, many of the disputed documents would be duplicative of material Defendants have already received or will receive. Documents relevant to Plaintiffs' claims and Defendants' defenses will be produced in the ordinary course in response to the dozens of broad document requests Defendants have served. Information concerning Plaintiffs' contentions have been or will be disclosed in the context of required contention disclosures and interrogatory responses here. Defendants still have three more months to serve additional document requests or interrogatories if they believe something is missing, and thereafter can depose Defendants' witnesses. And, as noted above, Plaintiffs have already agreed to produce all the documents they produced in *Moderna* and all the deposition testimony of their fact witnesses in *Moderna*. Defendants have not shown and cannot show any need for the additional materials they are seeking—*i.e.*,

"contentions, expert reports, … and responses to discovery requests" from a different litigation involving a different product and several different patents.

Finally, the burden of producing the disputed "contentions, expert reports, … and responses to discovery requests" is prohibitively high because those materials implicate significant third-party confidentiality concerns. Producing the documents would require Plaintiffs' attorneys to spend likely hundreds of hours identifying and redacting Moderna's confidential information, which appears in many of the documents. The burden of that effort far outweighs any marginal relevance the disputed materials may have [redacted]. *See VLSI*, 2018 WL 6930769 at *3 (refusing to compel "all documents from the prior … litigation" because "[t]hird-party confidential information is included throughout the subpoenaed discovery documents, expert reports, and depositions transcripts, and compelling production would require respondent's attorneys and paralegals to spend hundreds of hours reviewing the documents to locate the confidential information").

The Court should therefore deny Defendants' request for materials Plaintiffs produced in the *Moderna* litigation. In the alternative, if the Court grants Defendants' request, it should order Defendants to reciprocate by producing the same materials from the *Alnylam* litigation.

2. The Request For R&D Documents Is Largely Moot And Should Otherwise Be Denied

Defendants' request for R&D documents (ECF No. 79 at 3) is largely moot because, based on a reasonable investigation, Plaintiffs have already produced [redacted][1] Based on a reasonable investigation, Plaintiffs believe the foregoing documents constitute the universe of Plaintiffs' non-custodial documents concerning mRNA-LNP formulations. Defendants' request for additional disclosure should be denied.

First, contrary to Defendants' speculation, Plaintiffs are not excluding "research that is not expressly referenced in Dr. Heyes' declaration but nevertheless informed the experiments described in [his] declarations." ECF No. 79 at 4. Any such documents will be produced to the extent they are located via a reasonable search. Defendants could have confirmed that fact had

[1] Specifically, Plaintiffs have agreed to produce [redacted]. (Dkt. No. 79-2 at 1). In addition, in response to Defendants' RFP No. 26 seeking "[a]ll documents and things concerning the experiments, protocols, descriptions, or data underlying or referenced in a declaration submitted during the prosecution of a patent application underlying a Patent-in-Suit, including but not limited to the Declarations of Dr. James Heyes," Plaintiffs also made clear that they would produce [redacted]. *Id.*

they bothered to ask Plaintiffs over the course of months of meet-and-confer discussions, rather than raising the issue for the first time in their letter to the Court.

Second, there is no basis for Defendants' request for R&D documents, pre-clinical testing documents, and clinical testing documents relevant to ***non-mRNA*** nucleic acids. *Id.* at 4, 8. Defendants argue that such documents would be relevant to their invalidity defense under 35 U.S.C. 112, for purported lack of enablement and written description. *Id.* at 5-6, 9. But that argument fails because Defendants' invalidity defense concerns the use of ***mRNA*** with Plaintiffs' LNP formulations.[2] Plaintiffs have already agreed to produce [redacted]

Third, contrary to Defendants' assertion, Plaintiffs have not imposed "unilaterally-applied date ranges, including end dates apparently based on priority dates and start dates apparently selected arbitrarily." [redacted]. Rather, Plaintiffs have determined based on a reasonable investigation that [redacted] *See* ECF No. 79-2 at 1. [redacted]

Notwithstanding the foregoing, we address the four compromise proposals outlined in Defendants' letter—proposals that Plaintiffs would have considered had Defendants proposed them at any point over the *months* of the parties' discussions rather than for the first time the day before they filed their letter with the Court without waiting for a response:

- As to Defendants' request (ECF No. 79 at 6) for "the research underlying all declarations submitted in the prosecution of the asserted patents, including applications within the same family" (ECF No. 79 at 6), [redacted]
- As to Defendants' request for "lab notebooks and other research-related documents from named inventors from Jan. 1, 2001 onward" (*id.*)—*i.e.*, a period of nearly a *quarter-century*, including as to *irrelevant* patents, products, or subject matters—[redacted]

[2] For example, Defendants' invalidity contentions assert, *inter alia*, that the asserted patent claims are invalid under 35 U.S.C. § 112 because "[t]he specification does not recite any examples using mRNA" and because "the applicants submitted a declaration during prosecution of the '651 patent which argued that examples of achieving high encapsulation of plasmid DNA lipid particle formulations could not support a claim that this would achieve high encapsulation of mRNA lipid particle formulations." *See, e.g.*, Exhibit A, Defendants' Invalidity Contentions, at 28, 204-05. As already stated, Plaintiffs have produced pre- and post-priority date mRNA-LNP research, including lab notebooks, scientific presentations, final study reports, and COVID-19 vaccine development documents.

[redacted]

- Defendants' request for documents concerning "Protiva and/or Tekmira's research and development efforts concerning any LNP formulations" (*id.*)—even if they have *nothing to do* with the mRNA-LNP formulations at issue—is unworkable. The request as stated would call for production of every document relevant to [redacted] It would also require a massive effort to address third-party confidentiality concerns, which is a particular problem because [redacted] The request would also require time-consuming manual review of [redacted] All of this is unnecessary because Defendants already have Plaintiffs' documents relevant to Defendants' invalidity defense, as discussed *supra*.

- Defendants' request for Genevant's final study reports concerning lipids or LNP formulations for use with or comprising nucleic acids (*id.*) [redacted] As noted above, Defendants did not provide Plaintiffs an opportunity to respond to this proposal before including it in their letter to the Court. As such, Plaintiffs are currently assessing [redacted] Plaintiffs will follow up with Defendants once that assessment is complete.

Accordingly, the Court should deny Defendants' request for additional R&D documents subject to completion of Plaintiffs' assessment of whether they are able to produce [redacted]

3. The Request For Vaccine Development Documents Is Moot And Should Otherwise Be Denied

The Court should deny Defendants' request for "non-public documents concerning Plaintiffs' efforts to develop a SARS-COV-2 vaccine." ECF No. 79 at 7. The request is largely moot because [redacted] The request should otherwise be denied.

First, the requested documents would be rife with third-party confidential information that would likely require hundreds of hours to review and redact. *See*, *supra*, § 2.

Second, Defendants have other mechanisms to get the information they claim to need. Defendants argue that the documents are relevant to "[a]ny failed efforts by Plaintiffs to design a successful COVID-19 vaccine that would fall within the scope of the asserted patent claims," as purportedly relevant to "Defendants' pleaded invalidity defenses, as well as Plaintiffs' claim for damages." ECF No. 79 at 7. If that is truly what Defendants want, they are free to ask Plaintiffs' witnesses about failed vaccine development efforts, to the extent any exist, during depositions.

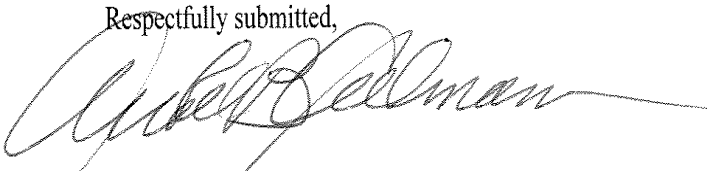
Additionally, Plaintiffs are willing to produce [redacted] Defendants' sweeping requests for additional disclosures should be denied.

4. The Request For Third-Party Documents Is Moot

Defendants' request for "[a]ll documents and things produced by third parties in the Current Litigation" is moot. ECF No. 79 at 8. [redacted] To the extent Defendants are now also seeking documents produced by third parties in Defendants describe as "voluntary production[s]," ECF No. 79 at 8, Plaintiffs represent that, [redacted]

We thank the Court for its consideration and assistance in this matter.

Respectfully submitted,



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cc: Counsel of record (by CM/ECF and electronic mail)